PharmaRisk™ Geriatric

Affiliated Genetics
2749 East Parleys Way, Suite 100
Salt Lake City, UT 84109
CLIA ID: 46D1077919

Affiliated Pharmarisk Geriatric Created for:

Patient:
HIPAA Compliant Fax:
Physician:
Address:
Collection Date:
Specimen Type:

Accession #:
Gender:
DOB:
Received Date:
Report Generated:

Key Test Findings

Pharmacogenetic Results

	Assay	Results	Phenotype	Clinical Consequences
✓	CYP2C19	*1/*1	Normal Metabolizer	Consistent with a typical CYP2C19 activity. This test did not identify risks for side effects or loss of efficacy with drug substrates.
⚠	CYP2C9	*1/*3	Intermediate Metabolizer	Consistent with a moderate deficiency in CYP2C9 activity. Potential risk for side effects or loss of efficacy with drug substrates.
🚩	CYP2D6	*1/*4 XN	Rapid or Normal Metabolizer	Consistent with typical or increased CYP2D6 activity. Potential risk for side effects or loss of efficacy with drug substrates.
🚩	VKORC1	-1639G>A A/A	High Warfarin Sensitivity	VKORC1 is the site of action of warfarin. The patient may require a substantial decrease in warfarin dose.

Cardiovascular/Thrombosis Risk Management

	Gene	Genotype	Phenotype	Clinical Consequences
✓	Factor II Factor V Leiden	20210G>A GG 1691G>A GG	No Increased Risk of Thrombosis	Unless other genetic or circumstantial risk factors are present, the patient is not expected to have an increased risk for thrombosis.
✓	MTHFR MTHFR	1298A>C AC 677C>T CC	No Increased Risk of Hyperhomocysteinemia.	The patient MTHFR function is slightly reduced and no significant hyperhomocysteinemia is expected.

Cardiovascular/Thrombosis Risk Management

✓ **Thrombophilia**

No Increased Risk of Thrombosis

Unless other genetic and/or circumstantial risk factors are present (ex: smoking, obesity…), estrogen-containing contraceptive and hormone replacement therapy can be used by the patient.

✓ **Hyperhomocysteinemia**

No Increased Risk of Hyperhomocysteinemia

MTHFR Enzyme Activity is normal.

Medication Guidance

Psychotropic Medications

Standard Precautions	Use With Caution	Consider Alternatives
Amphetamine (Adderall)	Bupropion (Wellbutrin)	Amitriptyline (Elavil)
Aripiprazole (Abilify)	Clozapine (Clozaril)	Atomoxetine (Strattera)
Citalopram (Celexa)	Dexmethylphenidate (Focalin)	Clomipramine (Anafranil)
Clobazam (Onfi)	Donepezil (Aricept)	Desipramine (Norpramin)
Desvenlafaxine (Pristiq)	Fosphenytoin (Cerebyx)	Doxepin (Silenor)
Dextroamphetamine (Dexedrine)	Lorazepam (Ativan)	Haloperidol (Haldol)
Diazepam (Valium)	Methylphenidate (Ritalin)	Imipramine (Tofranil)
Duloxetine (Cymbalta)	Naltrexone (Vivitrol)	Nortriptyline (Pamelor)
Escitalopram (Lexapro)	Olanzapine (Zyprexa)	Paroxetine (Paxil)
Gabapentin (Neurontin)	Oxazepam (Serax)	Risperidone (Risperdal)
Galantamine (Razadyne)	Perphenazine (Trilafon)	Trimipramine (Surmontil)
Iloperidone (Fanapt)	Phenytoin (Dilantin)	Venlafaxine (Effexor)
Lisdexamfetamine (Vyvanse)	Pimozide (Orap)	
Mirtazapine (Remeron)	Tetrabenazine (Xenazine)	
Paliperidone (Invega)		
Pregabalin (Lyrica)		
Sertraline (Zoloft)		
Thioridazine (Mellaril)		
Vortioxetine (Brintellix)		

Cardiovascular Medications

Standard Precautions	Use With Caution	Consider Alternatives
Atorvastatin (Lipitor)	Fluvastatin (Lescol)	Flecainide (Tambocor)
Carvedilol (Coreg)	Mexiletine (Mexitil)	Metoprolol (Lopressor)
Clopidogrel (Plavix)	Propafenone (Rythmol)	
Irbesartan (Avapro)	Rosuvastatin (Crestor)	
Lovastatin (Mevacor)	Warfarin (Coumadin)	
Nebivolol (Bystolic)		
Pitavastatin (Livalo)		
Prasugrel (Effient)		
Pravastatin (Pravachol)		
Propranolol (Inderal)		
Simvastatin (Zocor)		
Ticagrelor (Brilinta)		
Timolol (Timoptic)		

Pain Medications

Standard Precautions	Use With Caution	Consider Alternatives
Buprenorphine (Butrans, Buprenex)	Celecoxib (Celebrex)	Codeine (Codeine)
Carisoprodol (Soma)	Dihydrocodeine (Synalgos-DC)	Tramadol (Ultram)
Cyclobenzaprine (Flexeril, Amrix)	Flurbiprofen (Ansaid)	
Fentanyl (Actiq)	Hydrocodone (Vicodin)	
Hydromorphone (Dilaudid, Exalgo)	Oxycodone (Percocet)	
Meperidine (Demerol)	Tizanidine (Zanaflex)	
Methadone (Dolophine)		
Morphine (MS Contin)		
Oxymorphone (Opana, Numorphan)		
Piroxicam (Feldene)		
Tapentadol (Nucynta)		

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Other Medications

Standard Precautions	Use With Caution	Consider Alternatives
Darifenacin (Enablex)		Ondansetron (Zofran)
Dexlansoprazole (Dexilant)		
Esomeprazole (Nexium)		
Fesoterodine (Toviaz)		
Glimepiride (Amaryl)		
Glipizide (Glucotrol)		
Glyburide (Micronase)		
Lansoprazole (Prevacid)		
Metoclopramide (Reglan)		
Mirabegron (Myrbetriq)		
Omeprazole (Prilosec)		
Pantoprazole (Protonix)		
Rabeprazole (Aciphex)		
Tacrolimus (Prograf)		
Tamsulosin (Flomax)		
Tolbutamide (Orinase)		
Tolterodine (Detrol)		
Voriconazole (Vfend)		

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Test Details

Gene	Alleles Tested
CYP2C19	*2, *3, *4, *4B, *5, *6, *7, *8, *9, *10, *12, *17
CYP2C9	*2, *3, *4, *5, *6, *8, *10, *11, *12, *13, *15, *25, *27
CYP2D6	*2, *3, *4, *4M, *6, *7, *8, *10, *11, *12, *14A, *14B, *15, *17, *18, *19, *20, *29, *35, *38, *41, *44, *56, *5 (gene deletion), XN (gene duplication)
Factor II	20210G>A
Factor V Leiden	1691G>A
MTHFR	1298A>C
MTHFR	677C>T
VKORC1	1542G>C, -1639G>A, 1173C>T

Methodology:

Testing is performed on DNA extracted from a buccal swab. Samples are genotyped using Taqman® allele discrimination assays. The assays detect alleles listed above, including all common and most rare variants with known clinical significance at analytical sensitivity and specificity >99%.

Limitations:

The interpretations provided in this report are provided to assist health care providers, but they are not a treatment recommendation. Diagnosis and treatment remain the sole responsibility of the ordering physician. While the polymorphisms tested are important, other variants and mutations in these genes will not be detected. Mutations in other genes that could affect drug metabolism will not be detected. Non-genetic factors also affect metabolism. This test is not a substitute for clinical and therapeutic drug monitoring. This report does not address patient drug allergies or drug-drug interactions.

Signature:

Kenneth Ward M.D.

Date: 7/14/2014

CLIA FDA Statement:

This Laboratory Developed Test was developed and its performance characteristics determined by Affiliated Genetic, Inc. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing and has established and verified the test's accuracy. This test has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. These results are adjunctive to an ordering physician's diagnosis.

Appendix: Dosing Guidance

Amitriptyline (Elavil)

Possible Non-Response to Amitriptyline (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or prescribe amitriptyline at increased dose and monitor the plasma concentrations of amitriptyline and metabolites (there is insufficient data to calculate dose adjustment).

Atomoxetine (Strattera)

Possible Non-Response to Atomoxetine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider prescribing atomoxetine with careful titration and monitoring for reduced efficacy. There is insufficient data to calculate dose adjustment. Or consider alternative drug such as methylphenidate.

Celecoxib (Celebrex)

Possible Sensitivity to Celecoxib (CYP2C9 *1/*3 Intermediate Metabolizer)

Celecoxib can be prescribed at standard label recommended-dosage and administration. Evaluate response the first week and be alert to gastrointestinal adverse events.

Clomipramine (Anafranil)

Possible Non-Response to Clomipramine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or prescribe clomipramine at increased dose and monitor the plasma concentrations of clomipramine and desmethylclomipramine.

Codeine (Codeine)

Possible Increased Response to Codeine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer. Greatly increased morphine levels are expected and the patient is at high risk of toxicity when taking codeine. Avoid prescribing codeine and consider an alternative opioid or consider a non-opioid analgesic such as a NSAID or a COX-2 inhibitor. Unless contraindicated, available alternative opioids not sensitive to CYP2D6 function include: Fentanyl, Morphine, Hydromorphone, Oxymorphone and Tapentadol.

Desipramine (Norpramin)

Possible Non-Response to Desipramine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or prescribe desipramine at increased dosage and observe the patient for decreased efficacy. Adjust dosage in response to desipramine and metabolites plasma concentrations and clinical response.

Dihydrocodeine (Synalgos-DC)

Possible Altered Response to Dihydrocodeine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Increased conversion of dihydrocodeine to the more active metabolite dihydromorphine is expected in CYP2D6 rapid metabolizers. This may result in an exaggerated response. Adequate pain relief can be achieved by decreasing the dose in response to pain symptoms. Other opioids not metabolized by CYP2D6 (i.e. morphine, oxymorphone, buprenorphine, fentanyl, methadone and hydromorphone) may also be considered if signs of overdose (excessive sleepiness, confusion, or shallow breathing) are reported.

Donepezil (Aricept)

Possible Altered Response to Donepezil (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: when compared to a normal metabolizer, a rapid metabolizers has a 24% increase in donepezil clearance; the clinical significance of this increase is not well documented. Consider using a standard dosing regimen and adjust dosage in response to clinical response and tolerability.

Doxepin (Silenor)

Possible Non-Response to Doxepin (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or increase doxepin dose by 100%. Adjust maintenance dose according to nordoxepin plasma concentrations.

Flecainide (Tambocor)

Altered Response to Flecainide (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: titrate carefully and consider adjusting dose in response to plasma concentration and ECG monitoring OR consider alternative drug. Example of alternatives drugs not affected by CYP2D6 include: sotalol, disopyramide, quinidine and amiodarone.

Flurbiprofen (Ansaid)

Possible Sensitivity to Flurbiprofen (CYP2C9 *1/*3 Intermediate Metabolizer)

Flurbiprofen can be prescribed at standard label recommended-dosage and administration.

Fluvastatin (Lescol)

Possible Sensitivity to Fluvastatin (CYP2C9 *1/*3 Intermediate Metabolizer)

Increased fluvastatin plasma concentrations due to reduced CYP2C9 activity may occur, resulting in myotoxicity/hepatotoxicity. Consider monitoring the patient for treatment-related adverse effects and adjust dose as needed. Other adverse events predisposing factors include advanced age (≥65), diabetes, hypothyroidism, renal or hepatic impairments, high statin dose, CYP2C9 inhibitors, ABCG2 inhibitors and female gender.

Fosphenytoin (Cerebyx)

Moderate Sensitivity to Fosphenytoin (CYP2C9 *1/*3 Intermediate Metabolizer)

The genotype results indicate that the patient is an intermediate metabolizer of CYP2C9 substrates. Plasma concentrations of phenytoin are likely to increase resulting in an increased risk of mild to moderate neurological toxicity. Consider a standard loading dose and reduce maintenance dose by 25%. Evaluate response and serum concentrations after 7-10 days. Be alert to neurological concentration-related adverse events.

Haloperidol (Haldol)

Possible Non-Response to Haloperidol (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or prescribe haloperidol at standard dose and adjust dosage to achieve a favorable clinical response. Be alert to decreased haloperidol plasma concentrations.

Hydrocodone (Vicodin)

Possible Altered Response to Hydrocodone (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer. Increased conversion of hydrocodone to the more active metabolite hydromorphone is expected in CYP2D6 rapid metabolizers. Usually, adequate pain relief without an increase in adverse events can be achieved by using standard or lower hydrocodone doses. Other opioids not metabolized by CYP2D6 (i.e. morphine, oxymorphone, buprenorphine, fentanyl, methadone and hydromorphone) may also be considered if excessive side effects are reported.

Imipramine (Tofranil)

Possible Non-Response to Imipramine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or consider increasing imipramine dose and adjust dosage in response to imipramine and desipramine plasma concentrations.

Metoprolol (Lopressor)

Possible Non-Responder to Metoprolol (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: the patient may experience a decrease in the pharmacological effect when taking metoprolol at standard dosage. Heart Failure: Consider alternative beta-blockers such as bisoprolol or carvedilol or prescribe metoprolol at a higher dose. Other indications: Consider alternative beta-blockers such as bisoprolol or atenolol or or prescribe metoprolol at a higher dose. If metoprolol is prescribed, titrate dose to a maximum of 250% of the normal dose in response to efficacy and adverse events.

Mexiletine (Mexitil)

Altered Response to Mexiletine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: because mexiletine plasma concentrations may be decreased, consider adjusting dose in response to mexiletine plasma concentration and ECG monitoring until a favorable response in achieved.

Nortriptyline (Pamelor)

Possible Non-Response to Nortriptyline (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or prescribe nortriptyline at increased dose and monitor the plasma concentration of nortriptyline and hydroxynortriptyline.

Ondansetron (Zofran)

Possible Non-Response to Ondansetron (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: a substantially decreased antiemetic effect has been reported in these patients. Consider prescribing an alternative drug not metabolized by CYP2D6 such as granisetron.

Oxycodone (Percocet)

Possible Altered Response to Oxycodone (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer. Increased conversion of oxycodone to the more active metabolite oxymorphone is expected in CYP2D6 rapid metabolizers. Usually, adequate pain relief without an increase in adverse events can be achieved by using standard or lower oxycodone doses. Other opioids not metabolized by CYP2D6 (i.e. morphine, oxymorphone, buprenorphine, fentanyl, methadone and hydromorphone) may also be considered if excessive side effects are reported.

Paroxetine (Paxil)

Possible Non-Response to Paroxetine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or increase paroxetine dose and adjust dosage in response to efficacy.

Perphenazine (Trilafon)

Possible Non-Response to Perphenazine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: subjects with increased CYP2D6 function will metabolize perphenazine more rapidly which can result in sub-therapeutic drug concentrations. Consider a dose increase with close monitoring until a favorable response is achieved.

Phenytoin (Dilantin)

Moderate Sensitivity to Phenytoin (CYP2C9 *1/*3 Intermediate Metabolizer)

The genotype results indicate that the patient is an intermediate metabolizer of CYP2C9 substrates. Plasma concentrations of phenytoin are likely to increase resulting in an increased risk of mild to moderate neurological toxicity. Consider a standard loading dose and reduce maintenance dose by 25%. Evaluate response and serum concentrations after 7-10 days. Be alert to neurological concentration-related adverse events.

Pimozide (Orap)

Possible Non-Response to Pimozide (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: there is insufficient data to calculate dose adjustment and if pimozide is prescribed at standard dosing, monitor response and be alert to reduced efficacy. Standard starting dose: 1 to 2 mg/day (adult) or 0.05 mg/kg/day (children) - Doses may be increased to a maximum of 10 mg/day or 0.2 mg/kg/day.

Propafenone (Rythmol)

Altered Response to Propafenone (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers:titrate carefully and consider adjusting dose in response to plasma concentration and ECG monitoring OR consider alternative drug. Example of alternatives drugs not affected by CYP2D6 include: sotalol, disopyramide, quinidine and amiodarone.

Risperidone (Risperdal)

Possible Non-Response to Risperidone (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or prescribe risperidone and be extra alert to insufficient response and adjust dosage in response to clinical response and adverse events.

Tetrabenazine (Xenazine)

Unknown Sensitivity to Tetrabenazine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Individualization of dose with careful weekly titration is required. The first week's starting dose is 12.5 mg daily; second week, 25 mg (12.5 mg twice daily); then slowly titrate at weekly intervals by 12.5 mg to a tolerated dose. **The maximum daily dose in CYP2D6 rapid metabolizers is not defined. The maximum daily dose in normal metabolizers is 100 mg with a maximum single dose of 37.5 mg.** If serious adverse events occur, titration should be stopped and the dose of tetrabenazine should be reduced. If the adverse event (s) do not resolve, consider withdrawal of tetrabenazine.

Tramadol (Ultram)

Possible Increased Response to Tramadol (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer and is at high risk of toxicity when taking tramadol at standard dosing. Consider reducing tramadol dose by 30%. Careful monitoring for side effects and weekly titration are recommended. If toxicity, consider alternative opioids other than codeine or consider a non-opioid analgesic such as a NSAID or a COX-2 inhibitor. Unless contraindicated, available alternative opioids not sensitive to CYP2D6 function include: Fentanyl, Morphine, Hydromorphone, Oxymorphone and Tapentadol.

Trimipramine (Surmontil)

Possible Non-Response to Trimipramine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or consider prescribing trimipramine at an increased dose and then adjust dosage in response to trimipramine plasma concentrations.

Venlafaxine (Effexor)

Possible Non-Response to Venlafaxine (CYP2D6 *1/*4 XN Rapid or Normal Metabolizer)

Based on the genotype result, this patient MAY be a CYP2D6 rapid metabolizer, although the result is not definitive. The following recommendations apply for CYP2D6 rapid metabolizers: consider alternative drug or increase venlafaxine dose to a maximum of 150% of the normal dose and monitor venlafaxine and O-desmethylvenlafaxine plasma concentrations.

Warfarin (Coumadin)

Very High Sensitivity to Warfarin (CYP2C9 *1/*3)

Initiation Therapy: the expected therapeutic **dose is substantially lower than the usual one.** Consider using the following warfarin dose range provided in the FDA-approved label: **0.5-2 mg/day.** OR consider using a personalized dose as calculated by the provided pharmacogenetic algorithm. The estimated time to reach steady-state is more than 2-4 weeks. Frequent INR monitoring is recommended.

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Prescription Alert

DOB

This individual has been tested for gene variants that may affect medications prescribed.

GENE	RESULT
CYP2C19	Normal Metabolizer
CYP2C9	Intermediate Metabolizer
CYP2D6	Rapid or Normal Metabolizer
VKORC1	High Warfarin Sensitivity

Healthcare Providers: For up-to-date information concerning the impact of these genetic tests on drug precribing by may consult the PharmGKB database:

www.pharmgkb.org

Note:This patient has also been tested for common variants in the Factor II, Factor V, MTHFR, and ApoE genes.These results are available on the patient's medical records.